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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/889,616 | 05/08/2002 | Y. Tom Tang | PF-0662 USN | 6963 |

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| EXAMINER | |
|---|---|
| STEADMAN, DAVID J | |
| ART UNIT | PAPER NUMBER |
| 1652 | |

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/889,616 | TANG ET AL. | |
| | Examiner | Art Unit | |
| | David J Steadman | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Application*

**[1]** Claims 1-23 are pending in the application.

**[2]** The specification is objected to as applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

### *Lack of Unity*

**[3]** Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or goups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**Groups I-XLVIII**, claims 1-2, 8, and 15-16, drawn to the special technical feature of an isolated polypeptide, the first claimed method of making, and a pharmaceutical composition comprising a polypeptide, and the first claimed method of use, i.e., a method of using a pharmaceutical composition comprising a polypeptide for treating a disease. Group I recites SEQ ID NO:1, Group II recites SEQ ID NO:3, Group III recites SEQ ID NO:4,... ...and Group XLVIII recites SEQ ID NO:55.

**Groups XLIX-CIII**, claims 3-6 and 10-11, drawn to the special technical feature of an isolated polynucleotide, a recombinant polynucleotide, and a cell. Group XLIX recites a nucleic acid encoding SEQ ID NO:1 including SEQ ID NO:56, Group L recites the nucleic acid of SEQ ID NO:2, Group LI recites a nucleic acid encoding SEQ ID NO:3 including SEQ ID NO:58,... ...and Group CIII recites a nucleic acid encoding SEQ ID NO:55 including SEQ ID NO:110.

**Groups CIV-CLVIII**, claim 7, drawn to the special technical feature of a transgenic organism. Group CIV recites a transgenic organism comprising a nucleic acid encoding SEQ ID NO:1 including SEQ ID NO:56, Group CV recites a transgenic organism comprising the nucleic acid of SEQ ID NO:2, Group CVI recites a transgenic organism comprising a nucleic acid encoding SEQ ID NO:3 including SEQ ID NO:58,... ...and Group CLVIII recites a transgenic organism comprising a nucleic acid encoding SEQ ID NO:55 including SEQ ID NO:110.

**Groups CLIX-CCVI**, claim 9, drawn to the special technical feature of an isolated antibody that binds a polypeptide. Group CLIX recites SEQ ID NO:1, Group CLX recites SEQ ID NO:3, Group CLXI recites SEQ ID NO:4,... ...and Group CCVI recites SEQ ID NO:55.

**Groups CCVII-CCLXI**, claims 12-14, drawn to the special technical feature of a method of detecting a target polynucleotide. Group CCVII recites the nucleic acid of SEQ ID NO:56, Group CCVIII recites the nucleic acid of SEQ ID NO:57, Group CCIX recites the nucleic acid of SEQ ID NO:58,... ...and Group CCLXI recites the nucleic acid of SEQ ID NO:110.

**Groups CCLXII-CCCIX**, claim 17, drawn to the special technical feature of a method for screening a compound for effectiveness as an agonist of a polypeptide. Group CCLXII recites SEQ ID NO:1, Group CCLXIII recites SEQ ID NO:3, Group CCLXIV recites SEQ ID NO:4,... ...and Group CCCIX recites SEQ ID NO:55.

**Groups CCCX-CCCLVII**, claim 18, drawn to the special technical feature of a pharmaceutical composition comprising an agonist compound. Group CCCX recites SEQ ID NO:1, Group CCCXI recites SEQ ID NO:3, Group CCCXII recites SEQ ID NO:4,... ...and Group CCCLVII recites SEQ ID NO:55.

**Groups CCCLVIII-CDV**, claim 19, drawn to the special technical feature of a method for treating a disease by administering a pharmaceutical composition comprising an agonist compound. Group CCCLVIII recites SEQ ID NO:1, Group CCCLIX recites SEQ ID NO:3, Group CCCLX recites SEQ ID NO:4,... ...and Group CDV recites SEQ ID NO:55.

**Groups CDVI-CDLIII ,** claim 20, drawn to the special technical feature of a method for screening a compound for effectiveness as an antagonist of a polypeptide. Group CDVI recites SEQ ID NO:1, Group CDVII recites SEQ ID NO:3, Group CDVIII recites SEQ ID NO:4,... ...and Group CDLIII recites SEQ ID NO:55.

**Groups CDLIV-DI,** claim 21, drawn to the special technical feature of a pharmaceutical composition comprising an antagonist compound. Group CDLIV recites SEQ ID NO:1, Group CDLV recites SEQ ID NO:3, Group CDLVI recites SEQ ID NO:4,... ...and Group DI recites SEQ ID NO:55.

**Groups DII-DXLIX**, claim 22, drawn to the special technical feature of a method for treating a disease by administering a pharmaceutical composition comprising an antagonist compound. Group DII recites SEQ ID NO:1, Group DIII recites SEQ ID NO:3, Group DIV recites SEQ ID NO:4,... ...and Group DXLIX recites SEQ ID NO:55.

**Groups DL-DXCVII**, claim 23, drawn to the special technical feature of a method of screening a compound for effectiveness in altering expression of a polynucleotide. Group DL recites the nucleic acid of SEQ ID NO:56, Group DLI recites the nucleic acid of SEQ ID NO:57, Group DLII recites the nucleic acid of SEQ ID NO:58,... ...and Group DXCVII recites the nucleic acid of SEQ ID NO:110.

**[4]** The technical feature linking groups I-DXCVII is a polynucleotide. The inventions listed as Groups I-DXCVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. Although the polypeptides of Groups I-XLVIII, the polynucleotides of Groups XLIX-CIII, the polynucleotides of the transgenic organisms of Groups CIV-CLVIII, and the antibodies of Groups CLIX-CCVI share a common property or activity, the compounds are not regarded as being of similar nature because all alternatives do not share a common structure.

- According to PCT Rule 13.2 unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The nucleic acids of Groups XLIX-CIII, the polypeptides of Groups I-XLVIII, the transgenic organisms of Groups CIV-CLVIII, and the antibodies of Groups CLIX-CCVI share no special technical feature as the nucleic acids of Groups XLIX-CIII, particularly the nucleic acid of claim 11, encompasses nucleic acids that are not the same as the nucleic acid of the transgenic organism of Groups CIV-CLVIII and do not correspond to the polypeptide of Groups I-XLVIII and instead encompass nucleic acids that encode polypeptides that do not elicit the antibodies of Groups CLIX-CCVI.

- According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions of Groups I-DXCVII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups XLIX-CIII is a polynucleotide, which is shown by Database GenBank Accession Number R73178 to lack novelty or inventive step because Database GenBank Accession Number R73178 teaches a polynucleotide comprising at least 60 nucleotides of SEQ ID NO:1 and does not make it a contribution over the prior art.

- 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention. Accordingly, the methods of Groups CCLXII-CCCIX and CDVI-CDLIII do not have unity of invention with the polypeptides of Groups I-XLVIII.

**[5]** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**[6]** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**[7]** Claims 1-23 will be examined only to the extent the claims read on the elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

02-06-04

DAVID STEADMAN
PATENT EXAMINER